

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,290	09/29/2003	Gregory A. Demopulos	PH.1.0006.US2	3124
31629	7590 12/13/2005		EXAM	INER
OMEROS MEDICAL SYSTEMS, INC.			KWON, BRIAN YONG S	
1420 FIFTH AVENUE SUITE 2675			ART UNIT	PAPER NUMBER
SEATTLE, WA 98101			1614	

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

•	Application No.	Applicant(s)				
	10/674,290	DEMOPULOS ET AL.				
Office Action Summary	Examiner	Art Unit				
	Brian S. Kwon	1614				
The MAILING DATE of this communication	n appears on the cover sheet wit	h the correspondence address				
Period for Reply		NITHON OR THIRTY (20) RAVO				
A SHORTENED STATUTORY PERIOD FOR R WHICHEVER IS LONGER, FROM THE MAILIN - Extensions of time may be available under the provisions of 37 C after SIX (6) MONTHS from the mailing date of this communicatic - If NO period for reply is specified above, the maximum statutory p - Failure to reply within the set or extended period for reply will, by Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b).	IG DATE OF THIS COMMUNIC FR 1.136(a). In no event, however, may a re on. period will apply and will expire SIX (6) MONT statute, cause the application to become ABA	ATION. ply be timely filed 'HS from the mailing date of this communication. ANDONED (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on	29 September 2003.					
3) Since this application is in condition for all	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice un	der <i>Ex parte Quayle</i> , 1935 C.D.	11, 453 O.G. 213.				
Disposition of Claims						
4)⊠ Claim(s) <u>1-64</u> is/are pending in the application.						
	4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.		`				
6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) <u>1-64</u> are subject to restriction and	d/or election requirement.					
Application Papers						
9)☐ The specification is objected to by the Exa	miner.					
10)☐ The drawing(s) filed on is/are: a)☐	accepted or b) dojected to b	y the Examiner.				
 Applicant may not request that any objection to 	o the drawing(s) be held in abeyand	ce. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the co	•	• • •				
11) ☐ The oath or declaration is objected to by the	ne Examiner. Note the attached	Office Action or form PTO-152.				
Priority under 35 U.S.C. § 119	,					
12) Acknowledgment is made of a claim for for a) All b) Some * c) None of:	reign priority under 35 U.S.C. §	119(a)-(d) or (f).				
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority docur	ments have been received in Ap	plication No				
3. Copies of the certified copies of the		eceived in this National Stage				
application from the International Bu	` ' ' '					
* See the attached detailed Office action for a	a list of the certified copies not r	eceived.				
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Su	immary (PTO-413)				
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948 3) Information Disclosure Statement(s) (PTO-1449 or PTO/S 		/Mail Date ormal Patent Application (PTO-152)				
Paper No(s)/Mail Date	6) Other:					

Application/Control Number: 10/674,290

Art Unit: 1614

DETAILED ACTION

Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 40-64, drawn to a pharmaceutical product.
 - II. Claims 1-39, drawn to a process of using said product.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product (i.e., embolism, thorombosis, diabetes, autoimmune disease, etc...).

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Application/Control Number: 10/674,290 Page 3

Art Unit: 1614

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

- 2. If the applicant elects Group I invention, the elected invention is subject to further restriction as following.
 - I(a). Claims 40-44, 51-55 and 62-64, drawn to a pharmaceutical solution comprising a plurality of restenosis inhibitor agent.

Art Unit: 1614

- I(b). Claims 40-47, 51-58 and 62-64, drawn to a pharmaceutical solution comprising restenosis inhibitors in combination with spasm inhibitory agent.
- I(c). Claims 40-44, 48-55 and 59-64, drawn to a pharmaceutical solution comprising restenosis inhibitors in combination with pain/inflammation inhibitor agents.
- I(d). Claims 40-50, drawn to a pharmaceutical solution comprising restenosis inhibitors in combination with pain/inflammation inhibitor agents and spasm inhibitory agent.

One practicing the invention of any of the above groups would not necessarily be required to practice any of the others. Further a reference which anticipates the invention of one of the above groups would neither anticipate or make obvious any of the other inventions. The search for above inventions would not be co-extensive, particularly as to the literature search required. Clearly each of the above inventions is capable of supporting it's own patent. Thus, restriction for examination purposes as indicated is proper.

- 3. If the applicant elects Group II invention, the elected invention is subject to further restriction as following.
 - II(a). Claims 1-14 and 21-39, drawn to a process of inhibiting restenosis in a vascular procedure comprising administering restenosis inhibitor agents.
 - II(b). Claims 1-17 and 21-23, drawn to a process of inhibiting restenosis and selectively inhibiting spasm in a vascular procedure comprising administering restenosis inhibitors in combination with spasm inhibitory agents.

II(c). Claims 1-14, 18-20 and 21-23, drawn to a process of inhibiting restenosis and selectively pain/inflammation in a vascular procedure comprising administering restenosis inhibitors in combination with pain/inflammatory inhibitory agent.

II(d). Claims 1-23, drawn to a process of inhibiting restenosis and selectively pain/inflammation and spasm in a vascular procedure comprising administering restenosis inhibitors in combination with pain/inflammatory inhibitory agent and spasm inhibitory agents.

One practicing the invention of any of the above groups would not necessarily be required to practice any of the others. Further a reference which anticipates the invention of one of the above groups would neither anticipate or make obvious any of the other inventions. The search for above inventions would not be co-extensive, particularly as to the literature search required. Clearly each of the above inventions is capable of supporting it's own patent. Thus, restriction for examination purposes as indicated is proper.

4. In addition, applicant is required under 35 U.S.C. 121 to elect a single disclosed species (e.g., the specific compound from (i) "restenosis inhibitor agent", (ii) "spasm inhibitor agent" or (iii) "pain/inflammation inhibitory agent" exemplified in page 62-84 of the instant specification) under the instant claims of the elected Group. Moreover, whatever specific compound is ultimately elected, applicants are required to list all claims readable thereon.

With the election of a specific exemplified compound, a generic concept will be identified by the examiner as the inventive group for examination.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

Application/Control Number: 10/674,290

Art Unit: 1614

be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Page 6

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

- 6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon
Patent Examiner

AU 1614